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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,283	11/13/2001	Carl-Axel Bauer	06275-150003	5064

7590 07/30/2002

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/30/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,283

Applicant(s)

BAUER ET AL.

Examiner

Jennifer M Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The amendment filed May 7, 2002 have been received and entered into the application. Accordingly claims 1-8 and 10 have been cancelled and new claims 11-25 has been added.

1. Applicants' arguments and declaration filed May 7, 2002 have been fully considered but they are not persuasive.

Applicants argue that the results obtained for these parameters indicate a significant improvement in both of the measured parameters for the budesonide/formoterol-treated patients, as compared to the patients treated with either budesonide **alone** or formeterol **alone**. Thus, the results of this study indicate, unexpectedly, that it is possible to treat even moderate to severe COPD patients with excellent, long-term results using the claimed method.

Applicants' data may well be sufficient to show that combination of budesonide/formoterol-treated patients had a significant improvement compared to the patients treated with either budesonide alone or formoterol alone. However, there is no independent data by which the Examiner can make a reasonable determination of **synergistic effect** is present on the

combination of budesonide/formoterol gives greater than additive effect in treatment of COPD. Accordingly, one skilled in this art would find ample motivation from the prior art of record to combine the well known budesonide and formoterol together, of known properties where the results obtained thereby are no more than the additive effect of the ingredients.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of January 29, 2002 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9 and 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cazzola et al(U) of record and Nederland

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Tijdschrift Voor Geneeskunde (V) of record in view of Saunders Manual of Medical Practice(W).

Carling et al. on the abstract, page 4, lines 23-29, page 7-9(examples), and page 10 (claims), teach a medicament containing effective amounts of formoterol and budesonide in combination for simultaneous, sequential or separate administration by inhalation in treatment of respiratory disorder with effective amounts within Applicants' range set forth in claim 9.

Cazzola et al. on the abstract teaches that formoterol is effective in patients with chronic obstructive pulmonary disease.

The V reference on the abstract teaches the inhalation of budesonide is useful in the treatment of chronic obstructive pulmonary disease.

The W reference discloses on the Contents (part III), that chronic obstructive pulmonary disease as Respiratory disease.

The difference between Carling reference and Applicants' claimed invention is the use of Carling's medicament in treatment of chronic obstructive pulmonary disease (COPD).

However, it would have been obvious to skilled artisan to employ the Carling's medicament in treatment of COPD since COPD is well known respiratory disease as disclosed by the W

reference. Further, each of active agents (budesonide and formoterol) utilized in Carling's medicament are individually known to treat COPD conditions as well. The skilled artisan would have been motivated to employ Carling's medicament in treatment of COPD with reasonable expectation of success since each of the active agents utilized in Carling's medicament are well known individually for treating respiratory disease, COPD.

The amounts of active agents to be used, flavors, and surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulation.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

It is suggested that Applicants to submit a data and a clear explanation of how the data establishes synergistic effect in a declaration form for a favorable consideration.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer M Kim whose telephone number is 703-308-2232. The examiner can normally be reached on 8:30AM - 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
July 19, 2002